EXHIBIT 1

Get Email Updates:

ARCOS
BCM Online
Chemical Import/Export Declarations
CSOS (Controlled Substances Ordering System)
Theft/Loss Reporting
Import/Export
Medical Missions
Quotas
Registrant Record of Controlled Substances Destroyed
Regulated Machines (Tableting and Encapsulating)
Submit a Tip to DEA
Year-End Reports

SECTION 5.0 - TRANSACTION RECORD

5.1 TRANSACTION RECORD

Controlled substance transactions are reported using the ARCOS *transaction record*. This section discusses the *transaction record* fields that apply to all manufacturers and distributors of reportable controlled substances. Section 6 discusses *transaction record* fields that apply ***only*** to manufacturers.

The ARCOS *transaction record* has two formats: one format for reporting controlled substance transactions on magnetic tape, cartridge, or diskette (automated reporting) and another, slightly different format, for reporting transactions on DEA Form 333 (manual reporting). Exhibit 5.1: Transaction Record Formats, illustrates the record layouts for both formats. The differences between the two formats are:

1. The automated reporting format contains an additional field, the *document Identifier* field, which identifies the transaction as having been generated by an automated system.
2. The *transaction date* field is a ***six-digit*** field in the automated reporting format and a ***five-digit*** field in the manual reporting format.
3. The *quantity* field is an ***eight-position*** field in the automated reporting format and a ***six-position*** field in the manual reporting format

FIELD NAME	AUTOMATED			MANUAL (DEA Form 333)		
	FIELD #	FIELD LENGTH	POSITION LOCATION	FIELD #	FIELD LENGTH	COLUMN LOCATION
REPORTING REGISTRANT NUMBER	1	9	1-9	1	9	1-9
TRANSACTION CODE	2	1	10	2	1	10
ACTION INDICATOR (FORMERLY DELETE INDICATOR)	3	1	11	3	1	11
NATIONAL DRUG CODE (NDC NUMBER)	4	11	12-22	4	11	12-22
QUANTITY	5	8	23-30	5	6	23-28
UNIT	6	1	31	6	1	29
ASSOCIATE REGISTRANT NUMBER	7	9	32-40	7	9	30-38
DEA ORDER FORM NUMBER	8	9	41-49	8	9	39-47
TRANSACTION DATE	9	6	50-55	11-13	5	60-64
CORRECTION NUMBER (FORMERLY LOT NUMBER)	10	8	56-63	9	8	48-55
STRENGTH	11	4	64-67	10	4	56-59
TRANSACTION IDENTIFIER	12	10	68-77	14	5	65-69
DOCUMENT IDENTIFIER	13	3	78-80	NONE	NONE	NONE

Exhibit 5.1: Transaction Record Formats

5.2 DEA FORM 333: DUPLICATING DATA

ARCOS uses the equal sign, "=", to indicate that the data recorded in a *transaction record* field on DEA Form 333 is to be duplicated in subsequent *transaction records*. Under ARCOS the "=" is called the "duplicate sign." The duplicate sign (=) may be used to avoid repeatedly writing identical data within a field. The duplicate sign (=) ***must*** be coded in the first position of each field being duplicated. Examples applying to sections 5.2 and 5.2.1 illustrating the use of the duplicate sign are found in:

1. Exhibit 5.2: Using the Duplicate Sign, Single Reporter and
2. Exhibit 5.3: Using the Duplicate Sign, Central Reporter

5.2.1 DEA Form 333: Duplicating Transaction Date

The *transaction date* field is composed of three segments: Fields 11, 12, and 13 (year, month, and day). These three segments ***must*** be considered one, single field for duplicating purposes. Therefore, the entire *transaction date* ***must be the same*** when using the duplicate sign.

Exhibit 5.2: Using the Duplicate Sign, Single Reporter

Exhibit 5.2: Using Duplicate Sign: Single Reporter

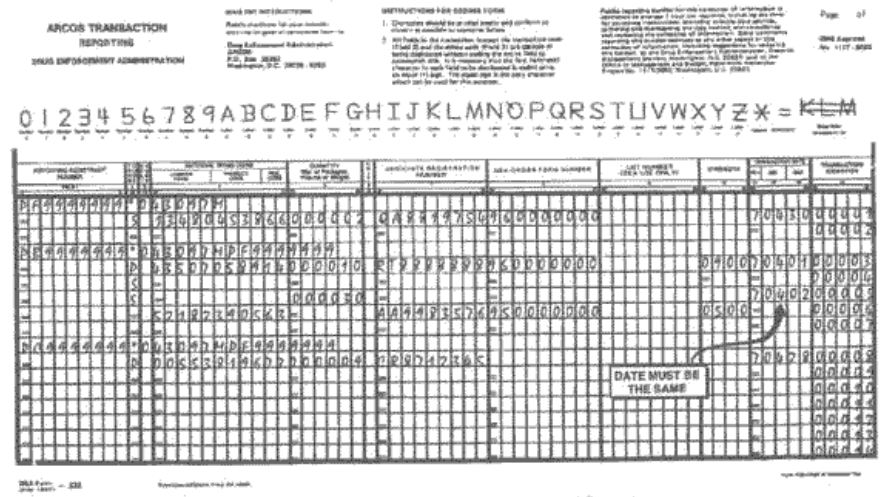


Exhibit 5.3: Using the Duplicate Sign, Central Reporter

Exhibit 5.3: Using the Duplicate Sign, Central Reporter

5.3 REPORTING REGISTRANT NUMBER

5.3.1 Definition: Reporting Registrant Number

The *reporting registrant number* is the DEA registration number identifying the location where the controlled substance activities being reported have occurred. This is a 9-character field.

5.3.2 Specifications: Reporting Registrant Number

a. Field Number:	1
b. Field Name:	*reporting registrant number*
c. Field Length:	9 Characters
d. Positions/Columns:	1-9
e. Type:	Alphanumeric
f. Special Rules:	

1. Mandatory Entry
2. Use Capital Letters for Alphabetic Data
3. Position/Column 1 is always 'P' or 'R'

5.3.3 Discussion: Reporting Registrant Number

A central reporter uses its own registrant reporting number when reporting for itself and the subsidiaries's registrant reporting number when reporting for a subsidiary.

5.4 TRANSACTION CODE

5.4.1 Definition: Transaction Code

The *transaction code* is a single-character field which identifies each specific ARCOS-reportable activity.

5.4.2 Specifications: Transaction Code

a. Field Number:	2
b. Field Name:	*transaction code*
c. Field Length:	1 Character
d. Position/Column:	10
e. Type:	Alphanumeric

f. Special Rules:

1. Only Specific Codes Permitted
2. Mandatory Entry
3. Use Capital Letters for Alphabetic Data

5.4.2 Specifications: Transaction Code

a. Field Number:	2
b. Field Name:	*transaction code*
c. Field Length:	1 Character
d. Position/Column:	10
e. Type:	Alphanumeric

f. Special Rules:

1. Only Specific Codes Permitted
2. Mandatory Entry
3. Use Capital Letters for Alphabetic Data

5.4.3 Discussion: Transaction Code

Manufacturers and distributors are responsible for reporting all ARCOS activities and inventories. The *transaction code* field identifies the reporting registrant's controlled substance acquisitions, dispositions, inventories, and miscellaneous transactions. The transaction codes listed below have been grouped into four categories for ease in selecting the correct code under which to report a specific business or manufacturing activity. These four categories are: inventory, acquisition, disposition, and miscellaneous. They are discussed in detail in Section 5.5 through 5.7. **See Appendix 1, ARCOS Transaction Matrix: Automated Reports** or **Appendix 2, ARCOS Transaction Matrix: Manual Reports**, to determine which fields must be completed for a specific *transaction code*.

Inventory Transaction Codes

transaction code 1: Schedule Change Inventory
transaction code 3: Year-End Inventory
transaction code 4: Year-End In-Process Inventory (manufacturers only)
transaction code 5: Special Inventory
transaction code 8: No Year-End Inventory

Acquisition Transaction Codes (Increases to Inventory)

transaction code P: Purchase or Receipt
transaction code R: Return
transaction code V: Unsolicited Return
transaction code G: Government Supplied
transaction code W: Recovered Waste (manufacturers only)
transaction code M: Manufactured (manufacturers only)
transaction code L: Reversing (manufacturers only)
transaction code J: Return of Sample to Inventory (manufacturers only)

Disposition Transaction Codes (Decreases to Inventory)

transaction code S: Sale, Disposition, or Transfer
transaction code Y: Destroyed
transaction code T: Theft
transaction code Z: Receipt by Government (seizures, samples, etc.)
transaction code N: Nonrecoverable Waste (manufacturers only)
transaction code U: Used in Production (manufacturers only)
transaction code Q: Sampling (manufacturers only)
transaction code K: Used in Preparations (manufacturers only)

Miscellaneous Transaction Codes

transaction code 7: No ARCOS Activity for the Current Reporting Period
transaction code F: Reorder DEA Form 333
transaction code X: Lost-in-Transit

5.5 INVENTORY TRANSACTION CODES

Transaction code 1, Schedule Change Inventory; *transaction code 3*, Year-End Physical Inventory; *transaction code 4*, In-Process Inventory; and *transaction code 5*, Special Inventory are used when reporting inventory data to DEA (ARCOS).

5.5.1 Code 1: Schedule Change Inventory

Transaction code 1, Schedule Change Inventory, is used when reporting bulk or dosage form products that become reportable controlled substances due to a controlled substance schedule change. Specific instructions will be provided by DEA (ARCOS) when a controlled substance schedule change affecting ARCOS reporting occurs.

Example:

Prior to March 21, 1991, glutethimide was a Schedule III controlled substance which was only reportable by ARCOS registrants actually manufacturing the drug. On March 21, 1991, glutethimide became a Schedule II controlled substance. At this point, glutethimide became reportable by all ARCOS registrants. All ARCOS registrants not previously reporting this controlled substance were required to report a Schedule Change Inventory Transaction (*transaction code 1*), if glutethimide was in their inventory on March 21, 1991.

Acquisition After Report

ARCOS registrants acquiring new stock after a Schedule Change Inventory report has been submitted, report this new stock as a "purchase" (*transaction code P*) or as another type of acquisition transaction when reporting that period's activities.

Out-of-Stock *or* Do Not Carry

ARCOS registrants that carry a newly-reportable controlled substance, but are out-of-stock ***or*** ARCOS registrants that do not carry a newly-reportable controlled substance ***must not*** report a Schedule Change Inventory. If an ARCOS registrant acquires the newly-reportable controlled substance at a later date, this acquisition would be reported as a "purchase" (*transaction code P*) or as another type of acquisition transaction when reporting that period's activities.

Exhibit 5.4: Schedule Change Reporting Requirements, summarizes reporting requirements when a controlled substance schedule change makes a formerly non-reportable controlled substance reportable.

Out-of-stock	None	Schedule Change Inventory Not Required
In-stock	*transaction code 1*	Schedule Change Inventory Required
Received After Schedule Change Date	*transaction code P* or Other Applicable Acquisition Code	Schedule Change Inventory Not Required

Exhibit 5.4: Schedule Change Reporting Requirements

5.5.2 Code 3: Year-End Physical Inventory

All ARCOS registrants are required to take a ***physical,*** year-end inventory (YEI). This inventory ***must*** reflect the ***actual amount*** of ***each*** reportable controlled substance on the registrant's premises as of the close of business on December 31st of ***each*** year. This is the ***only valid date*** which is accepted for *transaction code* 3. If the year-end inventory report is ***not*** dated December 31, the *transaction record* is ***rejected***. If year-end inventory transactions are included in the December or fourth quarter report, the reporting registrant ***must*** write **"YEI INCLUDED"** in the **"*Notes*"** block of the bar code label. This indicates that the December or fourth quarter report also contains the year-end inventory report and will ***prevent*** the registrant from being placed in a delinquent reporting status.

5.5.3 Code 4: Year-end In-process Inventory

On December 31st of each year, a manufacturer may have some quantities of controlled substances that are still in the manufacturing production chain (i.e., not in a bulk or finished dosage form). The amount of controlled substance at this stage of the production chain is termed an "In-process Inventory" *quantity*. Year-end In-process Inventory is reported using *transaction code 4*. The Year-end In-process Inventory is to be taken at the close of business on December 31st of the reporting year. This is the ***only date*** which will be accepted for transaction code 4. **See Section 6, Manufacturing Activities**, for examples of In-process Inventory reporting.

5.5.4 Code 5: Special Inventory

A Special Inventory is any inventory other than a Year-end, Year-end In-process, or Schedule Change Inventory being taken at the ***direction*** of DEA. Report a Special Inventory using transaction code 5.

5.5.5 Code 8: No Year-End Inventory

Transaction code 8 is used to report zero (0) year-end inventory. If, at the close of business on December 31st, an ARCOS registrant has no (i.e., zero) ***physical*** inventory for ***all*** the reportable controlled substances that it handles, the firm ***must*** report this ***lack*** of physical inventory to DEA (ARCOS). It is ***not*** necessary to report the lack of inventory for each reportable controlled substance that the firm has handled through the year. A single transaction code 8 is sufficient. The "no-year-end inventory" report will ***prevent*** DEA (ARCOS) from placing the registrant in a delinquent reporting status. *transaction code 8* requires the following fields:

- reporting registrant number
- transaction code 8
- *transaction date* (December 31st of each year)
- *transaction Identifier*

5.6 ACQUISITION TRANSACTION CODES

An ARCOS registrant can acquire controlled substances by buying them, by having previously sold controlled substances returned, or by receiving them from the government. If the ARCOS registrant is a manufacturer, the registrant can acquire controlled substances by four additional means: (1) manufacturing them, (2) recovering them from manufacturing waste, (3) having samples of controlled substances returned, or (4) by decomposing a substance into its component substances; one of which is a controlled substance. Acquisitions of controlled substances, irrespective of the manner in which they are acquired, increase the ARCOS registrant's inventory.

5.6.1 Code P: Purchase or Other Receipt

Transaction code P, purchase or other receipt, is used to report controlled substance acquisitions under three different scenarios:

1. The acquisition of a controlled substance by one ARCOS registrant from another.
2. The transfer of a controlled substance from one physical location to another.
3. Establishing the initial stock on hand of a controlled substance for a new ARCOS registrant

Controlled substances that are ***shipped directly*** from a supplier to an ARCOS registrant's customer (third party shipments) and are ***never physically on the registrant's premises***, (i.e., a drop shipment) are reported to DEA (ARCOS) by the supplier and the recipient. The ARCOS registrant ***must not***report these transactions.

5.6.2 Code R: Return

Transaction code R is used to report the receipt of returned controlled substances when the manufacturer or distributor ***requests*** their return. Returns reported under *transaction code R* do ***not*** necessarily involve a monetary transaction. Reportable controlled substances received by a supplier may include substances being returned for credit, salvage, re-work, or non-GMP (good manufacturing process) quality, as well as outdated or unused controlled substances.

5.6.3 Code V: Unsolicited Return

Transaction code V is used to report the receipt of an unsolicited return of a reportable controlled substance. An "unsolicited return" is a return that has ***not*** been ***requested*** by the manufacturer or distributor. The situations needing *transaction code V* are described below and summarized in Exhibit 5.5: Using Transaction Code V.

UNSOLICITED RETURN					
	SHIPPER'S IDENTITY	**SCHEDULE**	**ORDER FORM # REQUIRED?**	**TRANSACTION CODE**	**ASSOCIATE REGISTRANT NUMBER ENTRY**
1	Unknown	III narcotic	NO	V	"UNKNOWN"
2	Unknown	I, II	YES	V	"UNKNOWN"
3	Known	III narcotic	NO	V	USE SHIPPER'S DEA REGISTRATION NUMBER
4	Known	I, II	YES	V	USE SHIPPER'S DEA REGISTRATION NUMBER

Exhibit 5.5: Using Transaction Code V

Unknown Shipper

1. Use *transaction code V* when a Schedule III narcotic shipment is received ***without*** any identifying markings indicating the name of the firm that shipped the drugs. In the *associate registrant number* field (Field 7), enter "**UNKNOWN**" in all ***capital letters*** and ***left justified***.
2. Use *transaction code* V when a Schedule I or II product is received ***without*** the prior issuance of an order form (U.S. Official Order Forms - Schedules I & II) DEA Form 222, ***and without any*** identifying markings indicating the name of the firm that shipped the product. In the *associate registrant number* field (Field 7), enter "**UNKNOWN**" in all ***capital letters*** and ***left justified***. Additionally, a DEA Order Form Number ***must*** be acquired to cover the shipment. An "after-the-fact" DEA Order Form Number ***must*** be issued by the receiving firm using its ***own blank*** Order Form, ***after*** obtaining approval from the local DEA field office.

Known Shipper

1. Use *transaction code V* when a Schedule III narcotic shipment is received *without* prior notification and the shipper is *known*. If the registrant decides to keep the shipment, the registrant must obtain the approval of the local DEA field office. The ***shipper's*** DEA Registration Number is entered into the *associate registrant number* field (Field 7).
2. Use *transaction code V* when a Schedule I or II shipment is received ***without*** the prior issuance of an order form, DEA Form 222, and the shipper is ***known***. When such a shipment is received, the recipient firm ***must***: (1) obtain the approval of the local DEA field office to issue an "after-the-fact" DEA order form number and (2) issue the DEA order form number using its ***own blank*** order form. The ***shipper's*** DEA registration number is entered into the *associate registrant number* field (Field 7) and the order form number is entered in the *DEA order form number* field (Field 8).

5.6.4 Code G: Government Supplied

Transaction code G is used when the government supplies controlled substances or returns seized materials or samples to the reporting registrant. The registration number of the DEA or FDA divisional office is required in the *associate registrant number* field (Field 7). Contact your local DEA office to obtain the appropriate associate registrant number, if it is ***unknown***.

5.6.5 Manufacturing Acquisition Codes

The following acquisition transaction codes are discussed in Section 6, Manufacturing Activities:

transaction code W Recovered Waste (Manufacturers Only)
transaction code M Manufactured (Manufacturers Only)
transaction code L Reversing (Manufacturers Only)
transaction code J Return of Sample to Inventory (Manufacturers Only)

5.7 DISPOSITION TRANSACTION CODES

Controlled substances can be sold, destroyed, taken by the government, or stolen (theft). Under the manufacturing process there are a number of additional ways to dispose of controlled substances: (1) non-recoverable waste, (2) used in manufacturing, (3) distribution of samples, and (4) used in preparations. Dispositions of controlled substances, irrespective of the manner in which they are disposed, decrease the ARCOS registrant's inventory.

5.7.1 Code S: Sale, Disposition, or Transfer

Transaction code S is used when a controlled substance is physically transferred to another DEA registrant. This is ***not*** necessarily a monetary transaction. Samples to customers are included in this category. However, a sample that does ***not*** leave the ARCOS registrant's premises is reported as a *transaction code Q*. See Section 6, Manufacturing Codes. The sale of reportable controlled substances reduces the manufacturer's or distributor's inventory.

In cases where a controlled substance is shipped directly from a supplier to an ARCOS registrant's customer and is ***never physically*** on the registrant's premises (e.g., the registrant only does the billing), the registrant ***must not*** report the transaction. The supplier and the recipient do the reporting.

5.7.2 Code Y: Destroyed

Transaction code Y is used for reporting authorized destructions of controlled substances. Enter the registration number of the local DEA area office in the *associate registrant number* field (Field 7). If necessary, contact the DEA area office or the Data Systems Unit (ARCOS) to obtain the DEA registration number. For all destructions,

DEA Form 41, Registrants Inventory of Drugs Surrendered, ***must*** be filed with the local DEA area office. Exhibit 5.6: DEA Form 41, contains a sample form.

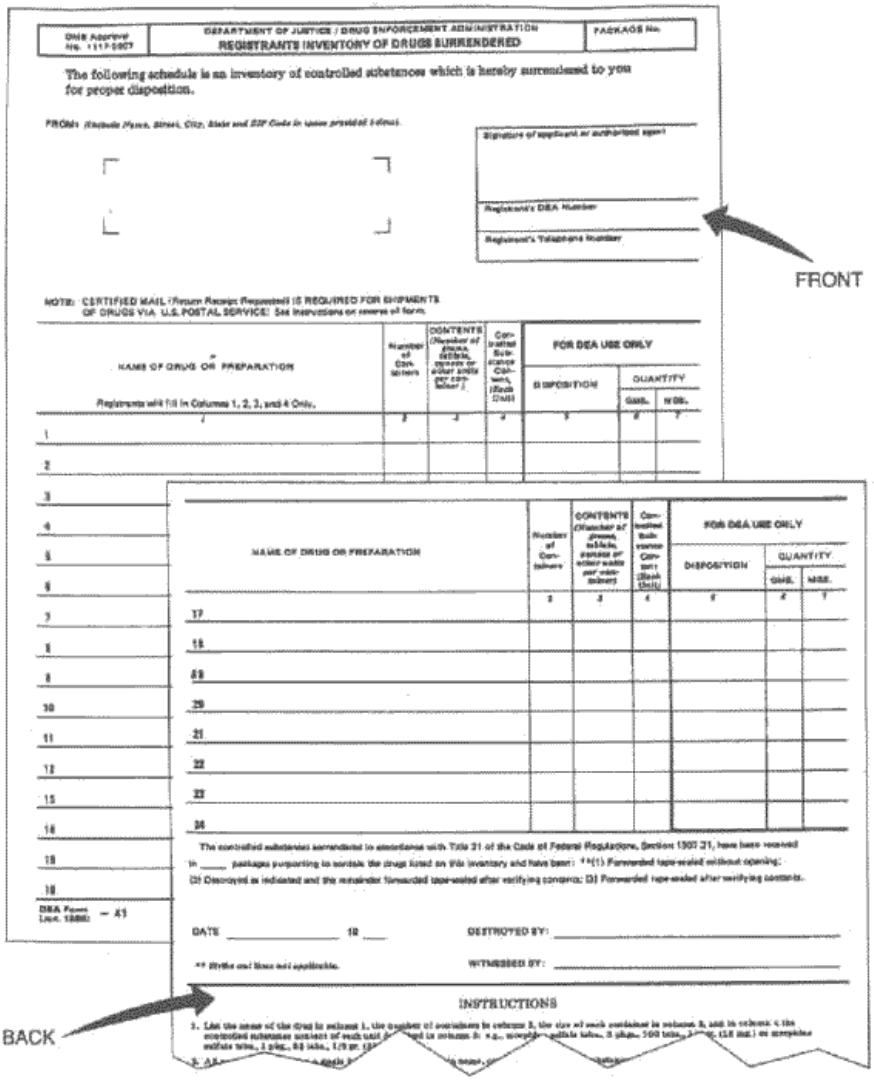


Exhibit 5.6: DEA Form 41

Exhibit 5.6: DEA Form 41

5.7.3 Code T: Theft

Transaction code T is used to report controlled substances ***stolen from your premises***. This does not eliminate the requirement to prepare an official theft report, U.S. Department of Justice, Drug Enforcement Administration, Report of Theft or Loss of Controlled Substances, DEA Form 106. Contact your local DEA office for further details. See Section5.8.3 Code X, for in-transit theft or loss. Exhibit 5.7: DEA Form 106, contains a sample theft report form.

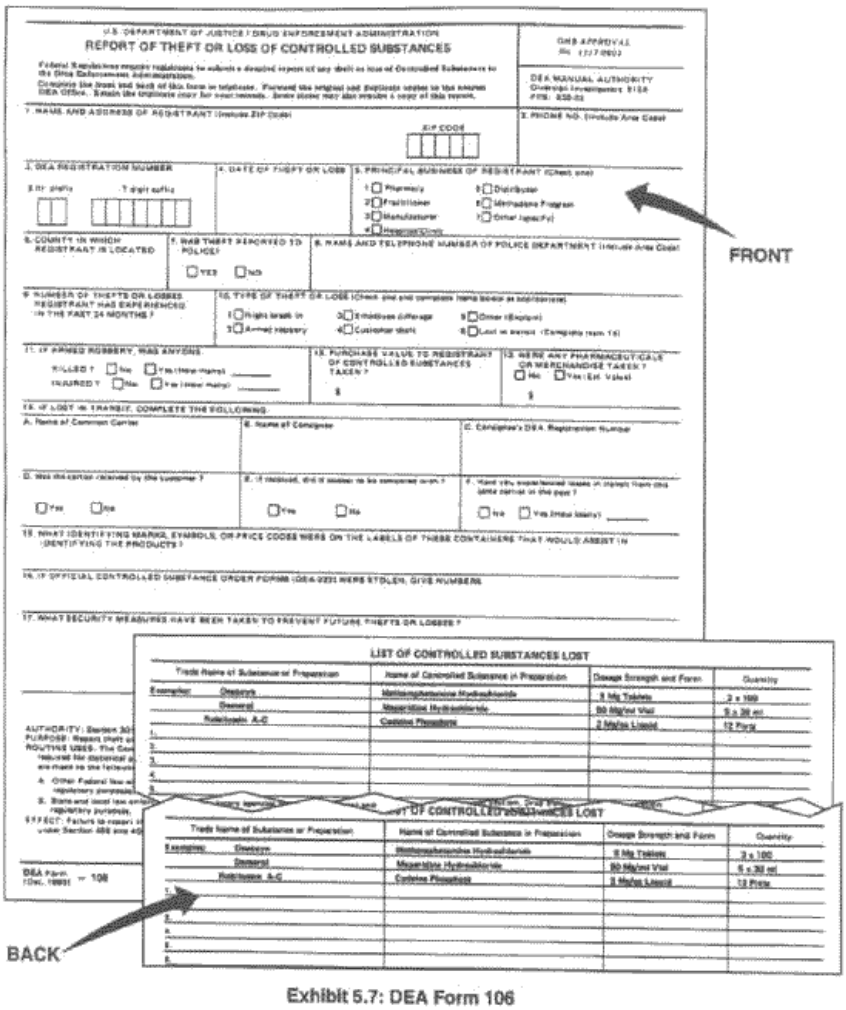


Exhibit 5.7: DEA Form 106

Exhibit 5.7: DEA Form 106

5.7.4 Code Z: Receipt by Government or Seizures

Transaction code Z is used to report the transfer (e.g., samples or seizure) of reportable controlled substances from a manufacturer or distributor to a government official. When a controlled substance is received by an agent of DEA or FDA, the DEA registration number of their Area Office must be entered in the *associate registrant number* field (Field 7). "**OFFICER**" is the entry in Field 7 for any other non-registered government official such as a customs officer; an agent of the Bureau of Alcohol, Tobacco, and Firearms; or state and local police officers. This entry ***must be*** in all ***capital letters*** and ***left justified*** within Field 7.

5.7.5 Manufacturing Disposition Codes

The following disposition transaction codes are discussed in Section 6, Manufacturing Activities:

transaction code N Nonrecoverable Waste (Manufacturers Only)
transaction code U Used in Production (Manufacturers Only)
transaction code Q Sampling (Manufacturers Only)
transaction code K Used In Preparations (Manufacturers Only)

5.8 MISCELLANEOUS TRANSACTION CODES

5.8.1 Code 7: No ARCOS Activity for the Current Reporting Period

Transaction code 7 is used to report the lack of controlled substance activity for the ***current*** reporting period. This ***lack*** of activity ***must be reported*** to DEA (ARCOS). *transaction code 7* is used when there has been ***no business activity for any and all*** controlled substances during the reporting period. It is not necessary to report no (i.e., zero) activity for each NDC product; a single *transaction code 7* will suffice. Submitting a *transaction code 7* will prevent DEA from placing the ARCOS Registrant in a delinquent reporting status. *Transaction code 7* requires the following fields:

- reporting registration number
- transaction code 7
- transaction date (last day of the *reporting period*)
- transaction identifier

5.8.2 Code F: Reorder DEA Form 333

Transaction code F is used to re-order a supply of DEA Form 333. The quantity requested cannot exceed 500 sheets for any single re-order. When the *quantity* field (Field 5) is left blank 100 forms will be sent. Complete only the following fields:

Field 1:	*reporting registrant number*
Field 2:	*transaction code F*
Field 5:	*quantity*
Field 14:	*transaction identifier*

5.8.3 Code X: Lost-in-Transit

Transaction code X is used by the seller to report the loss or theft of an in-transit shipment of a reportable controlled substance. It is reported ***in addition*** to the normal sales transaction (*transaction code S*). *Transaction code X* is an ***explanatory*** transaction code which does ***not*** affect an ARCOS registrant's inventory. Enter the DEA registration number of the intended purchaser in the *associate registrant number* field (Field 7). If the product lost in transit was a Schedule I or II controlled substance the selling ARCOS registrant ***must*** file an official theft report, U.S. Department of Justice, Drug Enforcement Administration, Report of Theft or Loss of Controlled Substances, DEA Form 106, with the local DEA office. Exhibit 5.7: DEA Form 106, contains a sample theft report form. If the ARCOS registrant purchasing the product still wants it, this registrant ***must*** supply a ***new*** order form with a ***new*** DEA order form number to ***replace*** the original one.

5.9 ACTION INDICATOR (Formerly DELETE INDICATOR)

5.9.1 Definition: Action Indicator

The *action indicator* was formerly called the *delete indicator*. The name has been changed to reflect the fact that the function of this field has been expanded.

The *action indicator* is a single-character field which initiates three different ARCOS data base operations: (1) the deletion of a *transaction record*, (2) the revision (adjustment) of ***data*** in a *transaction record*, and (3) the insertion of a late *transaction record*. These three data base operations are components of ARCOS error processing. **Section 7.5, Correcting Transaction Records**, contains a full discussion of the error processing.

5.9.2 Specifications: Action Indicator

a. Field Number:	3
b. Field Name:	*action indicator* (Formerly *delete indicator*)
c. Field Length:	1 Character
d. Position/Column:	11
e. Type:	Alphabetic

f. Special Rules:

1. Code "D" to delete a *transaction record*
2. Code "A" to adjust (revise) ***data*** in a *transaction record*
3. Code "I" to insert (add) a late *transaction record*
4. Use only capital letters
5. Leave blank when unused

5.9.3 Discussion: Action Indicator

See Section 7.5, Correcting Transaction Records for additional *action indicator* instructions.

5.10 NATIONAL DRUG CODE (NDC)

5.10.1 Definition: NDC

The National Drug Code (NDC) used by ARCOS is an 11-character code that identifies controlled substance products. This code is divided into three segments: the labeler code, the product code, and the package size code. General specifications are presented in Section 5.10.2, Specifications: NDC, followed by detailed specifications for each segment.

5.10.2 Specifications: NDC

a. Field Number:	4
b. Field Name:	NDC Number
c. Field Length:	11 Characters
d. Position/Column:	12-22
e. Type:	Alphanumeric

f. Special Rules:

1. Always coded except for *transaction codes 7, 8, and F*.
2. Entries must be made in each segment (Labeler Code, Product Code, Package Size Code).
3. Do ***not*** use hyphens (-), slashes (/), or blanks.
4. Do ***not*** enter product's name in lieu of the NDC.
5. Use capital letters for alphabetic data
6. See specific segment for additional special rules.

5.10.2.1 NDC Segment Specifications

Labeler Code

The National Drug Code Directory[1] defines a labeler as "...any firm that manufactures or distributes a drug product." The labeler code is assigned by the FDA.

a. Segment Name:	Labeler Code
b. Field Length:	5 Characters
c. Positions/Columns:	12-16
d. Type:	Alphanumeric

e. Special Rules:

1. Right justified.
2. Leading zeros ***must*** be entered to fill blank segment positions or columns.

Product Code

The National Drug Code Directory defines the product code as the segment that "identifies a specific strength, dosage form, and formulation for a particular labeler." The product code is assigned by the labeler.

a. Segment Name:	Product Code
b. Field Length:	4 Characters
c. Positions/Columns:	17-20
d. Type:	Alphanumeric

e. Special Rules:

1. Right justified.
2. Leading zeros *must* be entered to fill blank segment positions or columns.

Package Size Code

The National Drug Code Directory defines package size code as the segment that "identifies trade package sizes." The package size code is assigned by the labeler.

a. Segment Name:	Package Size Code
b. Field Length:	2 Characters
c. Positions/Columns:	21-22
d. Type:	Alphanumeric or "**" for bulk finished (e.g., unpackaged bulk dosage units) or bulk raw material (e.g., powder or liquid)

e. Special Rules:

1. Right justified.
2. Leading zeros *must* be entered to fill blank segment positions or columns.

1. U.S Department of Health and Human Services, Food and Drug Administration, *National Drug Code Directory*, Vol I, June 1995.

5.10.2.2 Formatting Summary

Exhibit 5.8: NDC Formatting Summary, briefly describes the formatting specifications for the NDC. These specifications apply to controlled substance transactions reported on automated media as well as DEA Form 333 for the following products:

1. Bulk Raw Powder
2. Bulk Dosage Formulations
3. Bulk Solutions
4. Trade Packages

TYPE OF MATERIAL	Bulk raw powder; bulk dosage forms; bulk solutions
LABELER CODE POSITIONS or COLUMNS: 12-16	alphanumeric, right justified, fill blanks with leading zeros
PRODUCT CODE POSITIONS or COLUMNS: 17-20	alphanumeric, right justified, fill blanks with leading zeros
PACKAGE CODE POSITIONS or COLUMNS: 21-22	**
TYPE OF MATERIAL	Trade Packages
LABELER CODE POSITIONS or COLUMNS: 12-16	alphanumeric, right justified, fill blanks with leading zeros
PRODUCT CODE POSITIONS or COLUMNS: 17-20	alphanumeric, right justified, fill blanks with leading zeros
PACKAGE CODE POSITIONS or COLUMNS: 21-22	alphanumeric, right justified, fill blanks with leading zero

Exhibit 5.8: NDC Formatting Summary

5.10.3 NDC Coding Examples

The NDC configuration for ARCOS reporting is composed of a 5-character Labeler Code, a 4-character Product Code, and a 2-character Package Code. When the NDC for a product ***does not*** conform to the configuration required under ARCOS, the following changes ***must*** be made in the configuration:

1. A leading zero ***must*** be added to the Labeler Code when this segment contains 4-characters.
2. A leading zero ***must*** be added to the Product Code when this segment contains 3-characters.
3. A leading zero ***must*** be added to the Package Size Code when this segment contains 1-character.
4. "**" ***must*** be placed in the Package Size Code segment when the product ***does not*** have a Package Size Code. The "**" indicates the product is in bulk form.

Transactions with incorrectly formatted NDC fields are rejected as erroneous and must be corrected and resubmitted. The exhibits in this section illustrate correct coding for the NDC field. Exhibit 5.9: Converting the NDC for a Non-bulk Product, illustrates how to convert an NDC for a non-bulk product to the format required by ARCOS. Exhibit 5.10: Converting the NDC for a Bulk Product, illustrates how to convert an NDC for a bulk product to the ARCOS format.

Fictitious Non-bulk Product (NDC Directory Configurations):

(a) 1234 - 1234 - 12 (b) 12345 - 123 - 34 (c) 12345 - 1234 - 7

Converting To ARCOS NDC Configurations

1. 01234 - 1234 - 12
   ^_____ leading zero added

2. 12345 - 0123 - 34
   12345 - ^_____ leading zero added

3. 12345 - 1234 - 07
   12345 - 1234 - ^_____ leading zero added

Exhibit 5.9: Converting the NDC for a Non-bulk Product

Fictitious Bulk Product (NDC Directory Configurations):

(a) 1234 - 1234 (b) 12345 - 123 (c) 12345 - 1234

Converting To ARCOS NDC Configurations

1. 01234 - 1234 - **
   01234 - 1234 - *^____"**"added
   ^_____ leading zero added

2. 12345 - 0123 - **
   12345 - 0123 - *^____"**"added
   12345 - ^_____ leading zero added

3. 12345 - 1234 - **
   12345 - 1234 - *^____"**"added

Exhibit 5.10: Converting the NDC for a Bulk Product

5.10.4 NDC Assignment

Identification of reportable controlled substances is always based on the Food and Drug Administration's National Drug Code (NDC). ***All*** *transaction records*, ***except*** for transaction codes 7, 8, and F ***must*** contain an NDC. Any *transaction record* with missing or invalid NDC will be rejected and must be corrected before being resubmitted. Contact the FDA at the address provided in **Exhibit 5.11: FDA Address**, for information about the National Drug Code.

Food and Drug Administration
Bureau of Drugs, Drug Listing Staff
5600 Fishers Lane
Center for Drug Evaluation & Research (CDER), HFD-95
Rockville, Maryland 20857
Telephone: (301) 594-1086
Hours: Monday-Friday 8:00am - 4:30pm ET

Exhibit 5.11: FDA Address

5.10.5 Submitting Labels

Pursuant to **21 CFR 1308.04**, firms holding a DEA registration as a manufacturer ***must*** provide DEA (ARCOS) with information about each new product, new dosage form, or other unit form containing ***any*** quantity of controlled substance. This information ***must*** be submitted within 30 days ***after*** manufacturing begins. However, DEA (ARCOS) will also accept this information ***prior to*** the beginning of manufacturing. Two labels or other documents (e.g., Drug Listing Form, FDA 2657) which reflect the following information ***must*** be submitted:

1. The trade name, brand name, or other commercial name of the product;
2. The generic or chemical name and quantity of each active ingredient, including both controlled and non-controlled substances (indicate what information is a proprietary trade secret);
3. The National Drug Code assigned to the product, if any; and
4. The weight of controlled substance as follows:

(1) Finished Dosage Unit Products:

Grams or milligrams per dosage unit

(2) Bulk Products:

Grams or milligrams per gram of powder
Grams or milligrams per milliliter of liquid

Send this information to DEA (ARCOS). The address is listed on the contact information page at the front of this handbook. The Data Systems Unit (ARCOS) strongly advises each manufacturer to send this information ***before*** submitting *transaction records* for their new products. A *transaction record* that does not have a matching NDC in the ARCOS NDC Dictionary is rejected as erroneous and must be resubmitted. Call the Data Systems Unit (ARCOS) to find out if the NDC information for your firm's new product has been added to the Dictionary.

All transactions for the new product that have occurred ***before*** the current reporting period, ***must*** be submitted as ***Late Transactions***. Otherwise, these transactions will be rejected as errors because their *transaction dates* are ***not*** within the current reporting period. **See Section 7, Edit Listings**, for Late Transaction instructions.

5.10.6 Pseudo NDC's

The pseudo NDC is a number developed by DEA (ARCOS) in consultation with the ARCOS registrant. A pseudo NDC may be requested from the DATA Systems Unit (ARCOS) when the NDC does not exist or is unavailable. This number enables ARCOS registrants to report transactions involving products for which an NDC is either unavailable or does not exist. Pseudo NDC's are ***not*** listed in the Food and Drug Administration's National Drug Code Directory.

5.10.7 Inner and Outer NDC Packages

A controlled substance product may have one NDC on an outer, larger package and a different NDC on the inner, smaller, individually-packaged units contained within the larger package. See Exhibit 5.12: Inner and Outer Packaging for an illustration. Either NDC may be used when reporting transactions and inventories. Care must be taken that the NDC ***corresponds*** to the product and package size being reported. A single NDC ***must never*** be used to identify two different package sizes of a product. The quantity reported will indicate the number of packages for that particular NDC.

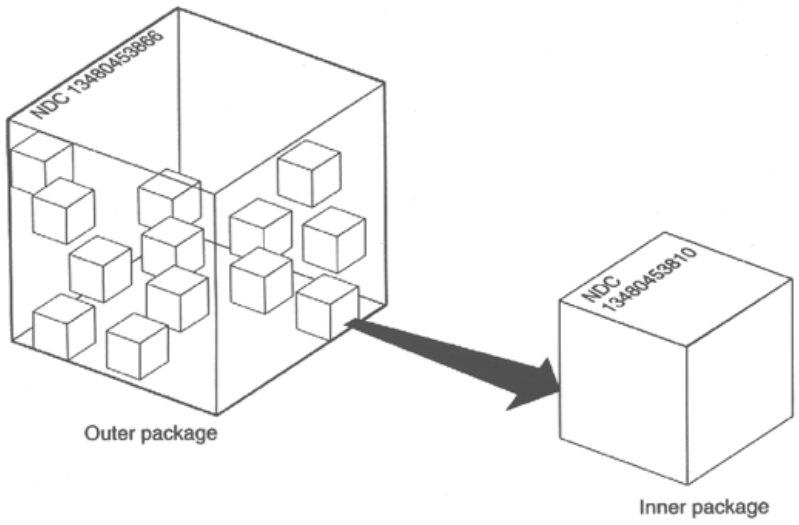


Exhibit 5.12: Inner and Outer Packages

Exhibit 5.12: Inner and Outer Packaging

5.11 QUANTITY

5.11.1 Definition: Quantity

The *quantity* field is a 6-digit (manual) or 8-digit (automated) numeric field containing the number of packages, weight, or volume being reported.

5.11.2 Specifications: Quantity

a. Field Number:	5
b. Field Name:	*quantity*
c. Field Length:	8 digits (automated) 6 digits (manual)
d. Positions/Columns:	23-30 (automated) 23-28 (manual)
e. Type:	Numeric

f. Special Rules:

1. Mandatory entry, except for *transaction codes 7, 8, and F*.
   Note: For *transaction code F* 100 forms will be sent when the *quantity* field is left blank.
2. *Quantity* field (Field 5) and *unit* field (Field 6) are mandatory entries when the controlled substance is measured in weight or volume.
3. When the *unit* field is blank, the quantity entered corresponds to the number of packages being reported.
4. Right justify entry.
5. Blanks are ***not*** permitted. Insert leading zeros in columns to the left of the number entered.
6. Enter whole numbers only. Do not truncate. Do not round. Do not use decimals, commas, etc.

5.11.3 Discussion: Quantity

5.11.3.1 Converting Fractional (Decimal) Quantities

All quantities ***must*** be reported in whole numbers that have neither been truncated nor rounded. To report a fractional quantity, convert the amount to units that do not require fractions. For example, to report a bulk quantity of 417.29 grams, the quantity must be converted to milligrams prior to being reported (i.e., 417.29 grams would be reported as a quantity of "417290" with a *Unit* Code of 2 which indicates milligrams. The following examples illustrate the correct coding of fractional quantities for both automated and manual reports:

Automated Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		001790062**	00417290	2	AB1234567	940590027	012194		1000	000000001	E25

Manual Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		001790062**	417290	2	AB1234567	940590027		1000	40121	00002

5.11.3.2 Coding the Quantity Field

Exhibit 5.13: Quantity Field Entries, illustrates *quantity* field coding.

NDC Number	PACKAGE DESCRIPTION	QUANTITY FIELD ENTRY	DESCRIPTION OF ITEM(S) REPORTED
99999-9999-**	Bulk Tablets	00025000	25,000 Tablets
88888-8888-01	Bottle of 500 Tablets	00000001	1 bottle of 500 Tablets
88888-8888-01	Bottle of 500 Tablets	00000005	5 bottles * 500 Tablets/bottle
77777-7777-04	4 fl oz Bottle	00000001	1 bottle of 4 fl oz
77777-7777-04	4 fl oz Bottle	00000003	3 bottles of 4 fl oz each (total=12 fl oz)
66666-6666-01	5ml Ampule (injection)	00000001	5 ml
66666-6666-01	5ml Ampule (injection)	00000005	5 ampules of 5 ml each (total = 25 ml)
55555-5555-02	Box of 10 each 5ml Ampules (injection)	00000001	1 box (50ml)
55555-5555-02	Box of 10 each 5ml Ampules (injection)	00000010	10 boxes (500ml) 500 ml in 10 boxes of 50 ml each

Exhibit 5.13: Quantity Field Entries

Appendix 4, Use of Quantity, Unit, and Strength Fields, contains additional examples of the relationships between various types of products (e.g., bulk raw powder, bulk dosage units, trade packages) and the *quantity*, *unit*, and *strength* fields in the ARCOS *transaction record*.

5.11.3.3 Reporting Bulk Raw Material

The *unit* (Field 6) and *strength* (Field 11 automated, Field 10 manual) fields must always be completed when reporting a Bulk Raw Material (package code = **) by weight or volume. See example below:

Example:

A manufacturer reports the synthesis (production) of a Schedule II bulk drug in raw powder form, 100 % pure. This product is chemically identified as Ecgonine Hydrochloride, molecular weight 221.69, NDC designation 00179-0062-**. The manufacturer sells 3,365.45gms of the product to another ARCOS registrant on January 21, 1997 under DEA order form number 940590027. The following example illustrates the coding for this transaction.

Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		001790062**	03365450	2	AB1234567	940590027	012197		1000	000000001	E25

Note: Reported as milligrams

Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		001790062**	003365	3	AB1234567	940590027		1000	70121	00001
PP1234567	S		001790062**	000450	2	AB1234567	940590027		1000	70121	00002

5.11.3.4 Reporting Bulk Dosage Form Material

When a finished bulk item (e.g., drum of capsules or tablets) is reported, it is typically assigned a double asterisk (**) for its NDC package code. The *quantity* field contains the total number of bulk dosage units being reported. See example below:

Example:

Manufacturer reports the production of large quantities of capsules, each capsule contains 10mg of Schedule II d-amphetamine hydrochloride, molecular weight 171.67, NDC designation 00023-0124-**. Manufacturer sells 865,400 capsules to another ARCOS Registrant on May 22, 1997 under DEA order form number 940079038. The coding example for this transaction is illustrated below.

Automated Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		000230124**	00865400		AB1234567	940079038	052297			000000001	E25

Manual Report (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		000230124**	865400		AB1234567	940079038			70522	00001

5.12 UNIT CODE

5.12.1 Definition: Unit Code

The *unit code* is a single-character, alphanumeric field used in conjunction with the *quantity* and *strength* fields to specify, by weight or volume, the amount of an NDC product being reported.

5.12.2 Specifications: Unit Code

a. Field Number:	6
b. Field Name:	*unit* code
c. Field Length:	1 Character
d. Position/Column:	31 (Automated) 29 (Manual)
e. Type:	Alphanumeric

f. Special Rules:

1. Must be completed for all substances reported by weight or volume.
2. May also be used to modify the Quantity field by indicating dozens or thousands of packages.

5.12.3 Weight and Volume Unit Codes

The *unit code* field must be completed for all transactions reported by weight or volume by entering one of the following unit codes:

1 = micrograms
2 = milligrams
3 = grams
4 = kilograms
5 = milliliters
6 = liters

5.12.4 Optional Unit Codes

Transaction records reporting NDCs that consist of complete package or dosage units ***do not*** require a unit code. However, the following ***optional*** unit codes may be used to report dozens or thousands of packages or dosage units.

1. D = Dozens:

   "D" indicates that the entry in the *quantity* field (Field 5) represents dozens of packages or dozens of dosage units.

2. K = Thousands:

   "K" indicates that the entry in the *quantity* field (Field 5) represents thousands of packages or thousands of dosage units.

Example:

A sale of 10,000 units can be reported with a number 10 in the *quantity* field (Field 5) and a "K" in the *unit code* field (Field 6) as follows:

Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		00065126810	00000010	K	AB1234567	940069028	081594			000000001	E25

Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		00065126810	000010	K	AB1234567	940069028			40815	00001

Appendix 4, Use of Quantity, Unit, and Strength Fields, contains additional examples of how to use *quantity*, *unit code*, and *strength* fields to report transactions involving NDC products in various forms, (e.g., bulk raw powder, bulk dosage units, trade packages).

5.13 ASSOCIATE REGISTRANT NUMBER

5.13.1 Definition: Associate Registrant Number

The *associate registrant number* is a 9-character field identifying the customer or supplier with which the transaction took place. For a sale enter the DEA registration number of the customer. For a purchase enter the DEA registration number of the supplier. Note: This field is labeled "Associate Registration Number" on DEA Form 333.

5.13.2 Specifications: Associate Registrant Number

a. Field Number:	7
b. Field Name:	*associate registrant number*
c. Field Length:	9 Characters
d. Position/Column:	32-40 (Automated) 30-38 (Manual)
e. Type:	Alphanumeric

f. Special Rules:

1. Use only DEA registration numbers.
2. Do not enter registrant's name.
3. Use only capital letters for alphabetic entries.

5.13.3 Discussion: Associate Registrant Number

The associate registrant number is required for ***each***transaction that increases or decreases the ARCOS registrant's inventory. The reporting registrant number and the associate registrant number ***cannot*** be the same. The *associate registrant number* field is ***not*** completed when reporting the following transaction codes:

Schedule Change Inventory	Code 1
Year-end Inventory	Code 3
Year-end In-process Inventory	Code 4
Special Inventory	Code 5
No Year-end Inventory	Code 8
No Activity	Code 7
Forms Request	Code F
Thefts	Code T
Manufacturing Transaction	Codes: M, W, L, J, N, U, K and Q.

5.13.3.1 Transfers to Exempt Organizations

Organizations which are exempt from registration with DEA under the Controlled Substances Act may acquire products containing controlled substances from an ARCOS registrant. When an ARCOS registrant provides an exempt organization with such a product, the registrant reports this transaction by entering one of the codes listed in Exhibit 5.14: Exempt Organization Codes, in the *associate registrant number* field, Field 7. All entries ***must*** be ***left justified*** and in ***all capital (upper case) letters.*** Any remaining positions or columns ***must*** be blank.

Exempt Organization	Entry in Field 7 (Left Justified)
Civil Defense Officials	CIVILDEF
FDA or DEA Drug Recall	RECALL
Law Enforcement Official	OFFICER
Ocean Vessels Receiving Controlled Substances	VESSELS
Native American Church	NATIVE
Military, Public Health Service, Bureau of Prisons, or Coast Guard	MILITARY

Exhibit 5.14: Exempt Organization Codes

5.13.3.2 Transfers Within a Firm

The transfer of a controlled substance from one DEA registration to another ***within*** the ***same firm***, ***must*** be treated as a normal sale (*transaction code S*) and purchase (*transaction code P*). For example, when a transfer from a manufacturer's inventory to a distributor's inventory takes place, two transactions are reported:

1. A sale (*transaction code S*) is reported under the manufacturing registration number. The distributor's DEA registration number is entered into the *associate registrant number* field (Field 7).
2. A purchase (*transaction code P*) is reported under the distributor's registration number. The manufacturer's DEA registration number is entered into the *associate registrant number* field (Field 7).

5.13.3.3 Destruction of Reportable Items

Enter the registration number of the DEA area office in the *associate registrant number* field when reporting all destructions of controlled substances (*transaction code Y*. If necessary, contact the DEA area office or the Data Systems Unit (ARCOS) to obtain the DEA registration number. DEA Form 41, Registrants Inventory of Drugs Surrendered, ***must*** be completed and filed with the local DEA area office. **Exhibit 5.6: DEA Form 41**, contains a sample form.

5.14 DEA ORDER FORM NUMBER

5.14.1 Definition: Order Form Number

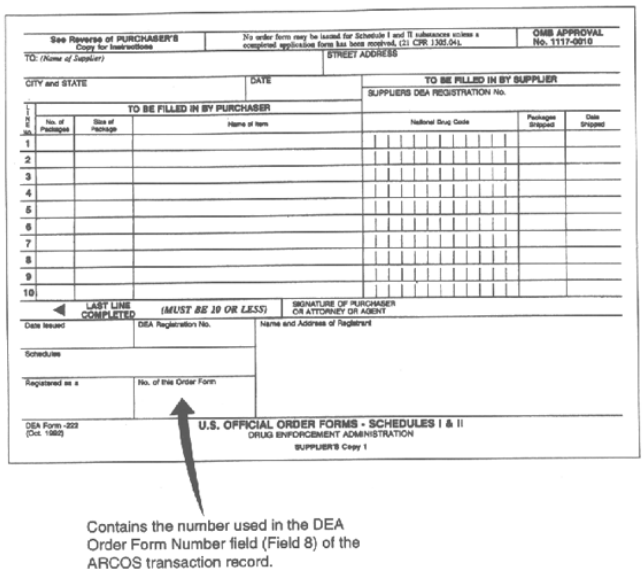
The *DEA order form number* field is a 9-character field in which the number of the order form (DEA Form 222) is entered. This field is used only when Schedules I and II controlled substances are transferred. An order form is illustrated in **Exhibit 5.15: DEA Form 222**.

5.14.2 Specifications: Order Form Number

a. Field Number:	8
b. Field Name:	*DEA order form number*
c. Field Length:	9 Characters
d. Position/Column:	41-49 (Automated) 39-47 (Manual)
e. Type:	Alphanumeric

f. Special Rules:

1. Mandatory for Schedules I and II
2. Use Only Capital Letters for Alphabetic Data.



Contains the number used in the DEA Order Form Number field (Field 8) of the ARCOS transaction record.

Exhibit 5.15: DEA Form 222

Exhibit 5.15: DEA Form 222

5.14.3 Discussion: Order Form Number

An order form, DEA Form 222, is required, pursuant to **21 CFR 1305**, for transfers of Schedules I and II controlled substances, but an order form is ***not*** required for Schedule III narcotics. Leave the *DEA order form number* field blank when reporting Schedule 3 narcotics. Copy 2 of each DEA order form ***must*** be forwarded to the supplier's local DEA area office. Do ***not*** mail ***any*** copies of DEA Form 222 to DEA (ARCOS).

5.14.3.1 Manufacturer Recall

When a manufacturer recalls a reportable product, the transaction must be reported as a purchase (*transaction code P*). Those firms returning the product, that are alsoARCOS registrants, report a sale (*transaction code S*). When a schedule I or II controlled substance is recalled, DEA, Diversion Control Division, may grant a limited exemption to the requirement for order forms. When such an exemption has been granted, the *DEA order form number* field (Field 8), must be completed with the word ***"RECALL"*** in ***all capital letters, left justified***. The remainder of the field must contain ***blank spaces***.

5.15 TRANSACTION DATE

5.15.1 Definition: Transaction Date

The *transaction date* is the ***actual*** date on which a reportable activity occurred. Exceptions are covered in Section 5.15.4, Discussion.

5.15.2 Specifications: Transaction Date

a. Field Number:	9 (automated) 11-13 (manual)
b. Field Name:	*transaction date*
c. Field Length:	6 digits (Automated) 5 digits (Manual)
d. Position/Column:	50-55 (Automated) 60-64 (Manual)
e. Type:	Numeric

f. Special Rules:

1. Automated and manual reporting have different formats.

5.15.3 Transaction Date Formats

Automated Format: **MMDDYY** (month, day, year)

Positions 50-51:	Month (01-12)
Positions 52-53:	Day (01-31)
Positions 54-55:	Year (last two-digits of the year 95, 96, etc.)
Coding Examples:	
January 1, 1996:	010196
November 11, 1997:	111197

Manual Format: **YMMDD** (year, month, day)

Column 60:	Year (last digit of the year, 0-9)
Columns 61-62:	Month (0I-12)
Columns 63-64:	Day (0I-31)
Coding Examples:	
January 1, 1996:	60101
November 11, 1997:	71111

5.15.4 Discussion: Transaction Date

A *transaction date* must be entered for all transactions. The *transaction date* ***must*** be the ***actual date*** on which the activity occurs. Except for manufacturing codes and delete, late, and adjustment transactions, the date of a transaction ***must never*** fall outside of the *reporting period* for the report being submitted.

Examples:

1. A *transaction record* with a June *transaction date* submitted with the July report is rejected unless it is a delete, late, or adjustment transaction (*action indicator* "D", "A", or "I").
2. Manufacturing activities associated with *transaction codes M, K, U, N, W, L, Q, and J* are reported as of the end of a quarter or the end of each year, even though these activities may actually have occurred on other dates during the year.

When using the duplicate sign (i.e. "=") to repeat a *transaction date* within a manual report, fields 11, 12 and 13 ***must*** be considered one field. In other words, the ***entire date must*** be the same when using the duplication sign. See **Exhibit 5.2: Using the Duplicate Sign, Single Reporter** or **Exhibit 5.3: Using the Duplicate Sign, Central Reporter**.

5.16 CORRECTION TRANSACTION

5.16.1 Definition: Correction Transaction

A Correction Transaction ***corrects*** a transaction that has been rejected by the data validation procedures. Rejected *transaction records* are listed in the Daily Transaction Processing Error Report.

5.16.2 Specifications: Correction Number (Formerly Lot Number)

a. Field Number:	10 (automated) 9 (manual)
b. Field Name:	*correction number* (formerly lot number)
c. Field Length:	8 digits 5 digits (Manual)
d. Position/Column:	56-63 (Automated) 48-55 (Manual)
e. Type:	Numeric

f. Special Rules:

1. Mandatory when submitting one or more Correction Transactions.

5.16.3 Discussion: Correction Number

Each Correction Transaction is identified by a unique, sequential *correction number*. The system uses this number when reprocessing the corrected *transaction record*. The *correction number* is listed on the error report and ***must*** be entered into the *correction number* field. The Correction Transaction is a component of ARCOS error processing. **Section 7.5, Correcting Transaction Records**, contains a full discussion of error processing including specific instructions for using the Correction Transaction.

5.17 STRENGTH

5.17.1 Definition: Strength

The *strength* field is used to report three different kinds of data: (1) the ***purity*** of a ***bulk raw*** material (2) the ***fractional portion*** of a standard NDC package size or (3) the ***percentage*** by which a package ***exceeds*** a standard NDC package size.

5.17.2 Specifications: Strength

a. Field Number:	11 (automated) 10 (manual)
b. Field Name:	*strength*
c. Field Length:	4 digits
d. Position/Column:	64-67 (Automated) 56-59 (Manual)
e. Type:	Numeric

f. Special Rules:

1. Mandatory entry for both *bulk raw* material and *partial* packages.
2. Fractional or Excess Package Size:

(a) Decimal is ***implied*** and ***never*** coded.

(b) Implied decimal point:

automated: between positions 66 & 67
manual: between columns 58 & 59

c) Decimal position:

automated: position 67
manual: column 59

5.17.3 Discussion: Strength

5.17.3.1 Strength Field: Bulk Raw Materials

The *strength* field ***must*** be completed when reporting a bulk raw material. All bulk raw materials and their level of purity are initially entered into the ARCOS drug ingredient dictionary. A *strength* field entry of 1000 (i.e. 100.0% purity) in a transaction involving a bulk raw controlled substance product indicates that the purity of the product being reported is the same as the corresponding NDC bulk raw material listed in the ARCOS drug ingredient dictionary. The *strength* field is required when reporting bulk raw materials. Any entry different from 1000 in this field indicates that the material being reported has a different purity than the bulk NDC listed in the ARCOS drug ingredient dictionary.

Example 1:

An NDC for a bulk raw material containing controlled substance with 90% purity is listed in the drug ingredient dictionary. The manufacturer sells a quantity of this material, unaltered, to a distributor, i.e. the manufacturer sells a powder containing 90% of a reportable controlled substance. Both manufacturer and distributor report this transaction (a sale for the manufacturer and a purchase for the distributor) with an entry of 1000 in the *strength* field, indicating that the purity of the product reported is equal to that of the product listed in the drug ingredient dictionary.

Example 2:

The same manufacturer as above (example 1) makes a batch of the same controlled substance mentioned above, but this time the purity of the batch is only 81%. The manufacturer wishes to sell some of this 81% pure controlled substance product using the NDC that is based on 90% purity. In order to do this, the manufacturer enters 0900 in the *strength* field, indicating that the purity of the material being reported is 90.0% of the 90% purity of the bulk NDC listed in the drug ingredient dictionary (.900 x .90 = .81).

5.17.3.2 Strength Field: Partial Packages

A partial package is an NDC package that has been opened and contains less than its original contents. To report a transaction with a partial package, enter the entire NDC in the NDC field (Field 4). Enter 1 with the correct number of leading zeroes in the *quantity* field (Field 5). In the *strength* field, enter the number of thousandths of the original contents of the NDC package that are being reported.

Example:

An NDC represents a bottle containing 100 LAAM hydrochloride tablets. An ARCOS registrant has an opened bottle of this NDC with 90 tablets remaining, 90% of the original package contents. To report this partial package, enter 1 with leading zeroes in the *quantity* field (Field 5) and "0900" in the *strength* field (Field 11 automated, Field 10 manual). The entry "0900" in the *strength* field indicates 90.0%. The decimal point in this percentage is implied, it is not to be coded. The following illustrations depict the correct automated and manual coding for reporting this example.

ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		11326000301	00000001		AB1234567	940690028	081594		0900	000000001	E25
											∧------- Implied decimal	

ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		11326000301	00000001		AB1234567	940690028		0900	40815	00001
										∧------- Implied decimal	

5.17.3.3 Strength Field: Combining Partial Packages

Two or more partial packages with the identical NDC may be reported as separate transactions or added together and reported as a single transaction, even when their combined contents are more than one complete package. The example below illustrates reporting ***two partial*** packages as a ***single*** transaction.

Example:

The standard NDC package size of Amytal tablets contains 100 tablets. An ARCOS Registrant needs to report two packages, each package containing less than 100 tablets. One package contains 90 Amytal tablets, while the other contains 25 Amytal tablets. The combined total of these two partial packages amounts to 115 tablets. This amount equals 115 percent of the standard package size.

To report 115 tablets as a single transaction, code a quantity of "1" in the *quantity* field (Field 5) and 1150 (115.0 percent of a full package) in the *strength* Field (Field 11 automated, Field 10 manual). Again, there is an ***implied*** decimal point between the two right-most positions in the *strength* Field.

ARCOS Automated Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)
PP1234567	S		10465592001	00000001		AB1234567	940690028	081594		1150	000000001	E25
											∧------- Implied decimal	

ARCOS Manual Report: (numbers in parenthesis indicate data field numbers)

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11-13)	(14)
PP1234567	S		10465592001	00000001		AB1234567	940690028		1150	40815	00001
										∧------- Implied decimal	

Refer to **Appendix 4, Use of Quantity, Unit, and Strength Fields**, for additional illustrations of ARCOS reporting relationships between various types of NDC products (i.e., bulk raw powder, bulk dosage units, trade packages) and the (a) *quantity*, (b) *unit code*, and (c) *strength* data fields in the ARCOS *transaction record*.

5.18 TRANSACTION IDENTIFIER

5.18.1 Definition: Transaction Identifier

The *transaction identifier* is a sequential number assigned by the reporting registrant to each *transaction record*.

5.18.2 Specifications: Transaction Identifier

a. Field Number: 12 (automated)
14 (manual)

b. Field Name:	*transaction identifier*
c. Field Length:	10 digits (automated) 5 digits (Manual)
d. Position/Column:	68-77(Automated) 65-69 (Manual)
e. Type:	Numeric

f. Special Rules:

1. The first *transaction identifier* within each report must always begin with the number one (1).
2. Each *transaction record* in a reporting period *must* have a unique *transaction Identifier*.
3. Leading zeroes must be included.
4. The original *transaction identifier* is repeated when submitting a correction, an adjustment, or a deletion.
5. A Late Transaction uses the next sequential *transaction identifier* from the initial report submitted.

5.18.3 Discussion: Transaction Identifier

The *transaction identifier* field for *transaction records* submitted by central reporters may use one of two configurations:

1. Continuous Sequence:

   Transaction records may be numbered in a continuous sequence.

2. Separate Sequences

   Transaction records for each reporting registrant may be numbered in separate sequences.

Example: Continuous Sequence

A central reporter submits a report for itself and two subsidiaries containing a total of 150 transactions. These records may be numbered sequentially and continuously "1" through "150."

Example: Separate Sequences

A central reporter submits a report for itself and three subsidiaries containing a total of 400 transactions. These records may be numbered "1" to "125" for the central reporters own registration number, "1" to "50" for the first subsidiary, "1" to "200" for the second subsidiary and "1" to "25" for the third subsidiary.

5.19 DOCUMENT IDENTIFIER

5.19.1 Definition: Document Identifier

The *document identifier* is used to distinguish reports submitted on magnetic media (i.e., diskette or tape) from reports submitted on DEA Form 333 coding sheets. The *document identifier* appears only in automated *transaction records*.

5.19.2 Specifications: Document Identifier

a. Field Number:	13
b. Field Name:	*document identifier*
c. Field Length:	3 Characters
d. Positions:	78-80
e. Type:	Alphanumeric

f. Special Rules:

1. "E25" is the only acceptable entry.
2. Only in automated *transaction records*.

5.19.3 Discussion: Document Identifier

No additional discussion.

Previous | **Table of Contents** | **Next**

HOME CONTACT US A-Z SUBJECT INDEX PRIVACY NOTICE WEBSITE ASSISTANCE

REGISTRATION

Applications
Tools
Resources
CMEA Required Training & Self-

REPORTING

ARCOS
BCM Online
Chemical Import/Export Declarations
CSOS (Controlled Substances Ordering System)

RESOURCES

Cases Against Doctors
Chemical Control Program
CMEA (Combat Meth Epidemic Act)
Controlled Substance Schedules
DATA Waived Physicians
National Prescription Drug Take Back Day
NFLIS
Publications & Manuals
Questions & Answers